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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,361	12/05/2001	Daniel F. Bischof	F-5800	4370

7590 03/23/2005

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8m

Office Action Summary	Application No. 10/008,361	Applicant(s) BISCHOF ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 37-65 is/are pending in the application.
 4a) Of the above claim(s) 1-26, 31-33 and 37-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/04 has been entered.

Response to Amendment

In the amendment filed 12/26/04, claim 27 was amended. Claims 1-34 and 37-65 remain pending. 1-26, 31-33 & 37-65 remain withdrawn, drawn to an invention nonelected with traverse in Paper No. 8

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber et al. (5,269,946) in view of Lin et al. (6,566,046). Goldhaber et al. (hereafter Goldhaber) discloses a system for collecting, separating and filtering whole blood components into storage containers. The system includes 4 bags (16/28/26/34) or containers seen to be equivalent to applicant's primary, platelet unit, plasma unit and auxiliary containers. The containers are integrally coupled to one another by tubing (29/30/32) to form a sterile blood processing set. The system further includes a filter (40) in-line with one of the containers to remove undesired components from the separated blood, such as white blood cells. Goldhaber also discloses that one of the bags may have an appendage or connector (C) that is sized and configured for connecting to additional tubing (see figures). Goldhaber also teaches that additive may be added to one of the containers of the system. Goldhaber also discloses that the assembly is a "closed" system (col. 5, lines 53-55).

Goldhaber does teach of storing platelets in one of the containers, however, it is well known in the art that it is beneficial to add an additive to separated blood cells, in this case platelets, to extend the life of the separated cells. Goldhaber also does not explicitly teach that the auxiliary container holding a platelet additive solution comprising

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an aqueous solution comprising sodium chloride, sodium citrate, sodium acetate, and sodium phosphate for conditioning the platelet concentrate for pathogen inactivation.

Lin et al. (hereafter Lin) teaches of a synthetic platelet storage, or additive, aqueous solution of sodium chloride, sodium citrate, sodium acetate, and sodium phosphate. As shown in figure 9B, the solution is held in a bag or container that is part of a whole blood separation system. The solution is used with the photo decontamination of platelets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select the platelet additive taught by Lin for use in the container system of Goldhaber for mixing the platelets collected within the container for subsequent storage or transfusion, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. With respect to the added limitation of the additive solution being contained in the auxiliary container "in an at least an amount sufficient" for mixing the platelet concentration and plasma to "achieve a predetermined ratio of additive solution and plasma and provide" the mixture "conditioned for a pathogen inactivation treatment" this limitation is considered to be an obvious variation of the concentration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose to have an amount of additive of an amount to achieve a predetermined ratio, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Further, the

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limitation with respect to conditioning for pathogen inactivation treatment is a recitation of the intended use of the device.

Response to Arguments

Applicant's arguments filed 12/26/04 have been fully considered but they are not persuasive. Applicant argues that Goldhaber et al. (hereafter Goldhaber) does not teach of a closed blood collection system comprising a synthetic platelet solution within an auxiliary container in an at least an amount sufficient for mixing the platelet concentration and plasma to achieve a predetermined ratio of additive solution and plasma and provide the mixture conditioned for a pathogen inactivation treatment as required by amended claim 27. Goldhaber does teach of storing platelets in one of the containers and it is well known in the art that it is beneficial to add an additive to separated blood cells, in this case platelets, to extend the life of the separated cells. The teaching of Lin et al. to add a platelet additive in the container system of Goldhaber for mixing the platelets collected within the container for subsequent storage or transfusion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 18th, 2005


PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762